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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,077	08/30/2001	Thomas Metzler	RDID01007US	2679

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 09/20/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicati n No.</b>		<b>Applicant(s)</b>	
	09/763,077		METZLER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	William H. Beisner		1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 Aug. 2001 (Pre. Amendment).
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other:  |

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## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 16 Feb. 2002 has been considered and made of record.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 16-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, line 12, recitation of "a semipermeable membrane" is indefinite because it is not clear if this membrane is the same or different from that recited at line 10.

Claims 29 and 30 are indefinite because the claims merely recite using a device without positively reciting method steps which include supplying the reagents and/or liquid required to perform the method intended of the preamble of the claims.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16, 17, 24, 25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Medicus et al. (US 4,450,076).

The reference of Medicus et al. discloses a dialyzer device which includes an external housing (32) with a cover (44). The device includes an inner housing (40) which includes wells (10) with a cap (18) and a semipermeable membrane (14) separating the interior of the wells (10) with respect to the liquid supply region defined by the external housing (32). The device

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includes means (52, 48, 36, 34) for moving and incubating the liquids contained on either side of the membranes.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medicus et al.(US 4,450,076).

The reference of Medicus et al. has been discusses above.

Claims 21 and 22 recite the volume of the well chamber and the volume of the supply chamber with respect to the volume of the well chamber.

While the reference of Medicus et al. is silent as to the specific volumes, the reference is drawn to a "small-sample dialyzer". In the absence of a showing of unexpected results and/or criticality, it would have been obvious to one of ordinary skill in the art to determine the optimum volumes of the chambers based merely on the specifics of the dialysis method to be performed in the device while maintaining the desired efficiency of the system.

12. Claims 21, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medicus et al.(US 4,450,076) in view of Riley et al.(US 3,623,611).

The reference of Medicus et al. has been discussed above.

Claim 26 requires that the inner housing be made of a bored blocks with a membrane fixed between two blocks so as to define a plurality of wells with membranes at a bottom of each well.

The reference of Riley et al. discloses that it is known in the art to form a multiple well device wherein the bottom of each well includes a membrane by fixing a membrane between bored blocks (See Figure 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the inner container of the primary reference in a

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manner as suggested by the reference of Riley et al. for the known and expected result of providing an alternative means recognized in the art for defining a plurality of wells with a membrane defining the bottom of each well. The technique of the reference of Riley et al. eliminates the need to individually cut each membrane for each well as is required of the primary reference.

With respect to the claimed volumes of claims 21 and 22, the reference of Riley et al. also discloses that it is known to employ sample chambers for dialysis devices with a volume of 0.001ml or less (See the abstract).

In the absence of a showing of unexpected results and/or criticality, it would have been obvious to one of ordinary skill in the art to determine the optimum volumes of the chambers based merely on the specifics of the dialysis method to be performed in the device while maintaining the desired efficiency of the system.

13. Claims 16, 17, 21, 22, 24, 25, 27, 28, 29 and 30/27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al.(Biotech. Prog.) in view of Medicus et al.(US 4,450,076).

The reference of Kim et al. discloses a method and device for the performance of biological reactions in a dialysis device (See Figure 4).

The instant claims differ by reciting that the device includes an inner housing with at least two wells.

The reference of Medicus et al. discloses a dialysis device which is known in the art and is similar in construction to that of the device disclosed by the reference of Kim et al. The device of Medicus et al. discloses an inner housing with a plurality of separate sample chambers (See

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Figure 5). Specifically the reference of Medicus et al. discloses a dialyzer device which includes an external housing (32) with a cover (44). The device includes an inner housing (40) which includes wells (10) with a cap (18) and a semipermeable membrane (14) separating the interior of the wells (10) with respect to the liquid supply region defined by the external housing (32). The device includes means (52, 48, 36, 34) for moving and incubating the liquids contained on either side of the membranes.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to perform the method disclosed by the reference of Kim et al. in a device as disclosed by the reference of Medicus et al. for the known and expected result of providing a device which would allow for a plurality of simultaneous reactions to be performed in a single dialysis system.

Claims 21 and 22 recite the volume of the well chamber and the volume of the supply chamber with respect to the volume of the well chamber.

While the reference of Medicus et al. is silent as to the specific volumes, the reference is drawn to a "small-sample dialyzer". In the absence of a showing of unexpected results and/or criticality, it would have been obvious to one of ordinary skill in the art to determine the optimum volumes of the chambers based merely on the specifics of the dialysis method to be performed in the device while maintaining the desired efficiency of the system.

14. Claims 21, 22, 26 and 30/26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al.(Biotech. Prog.) in view of Medicus et al.(US 4,450,076) and Riley et al.(US 3,623,611).



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The combination of the references of Kim et al. and Medicus et al. has been discussed above.

Claim 26 requires that the inner housing be made of a bored blocks with a membrane fixed between two blocks so as to define a plurality of wells with membranes at a bottom of each well.

The reference of Riley et al. discloses that it is known in the art to form a multiple well device wherein the bottom of each well includes a membrane by fixing a membrane between bored blocks (See Figure 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to manufacture the inner container of the primary reference in a manner as suggested by the reference of Riley et al. for the known and expected result of providing an alternative means recognized in the art for defining a plurality of wells with a membrane defining the bottom of each well. The technique of the reference of Riley et al. eliminates the need to individually cut each membrane for each well as is required of the primary reference.

With respect to the claimed volumes of claims 21 and 22, the reference of Riley et al. also discloses that it is known to employ sample chambers for dialysis devices with a volume of 0.001ml or less (See the abstract).

In the absence of a showing of unexpected results and/or criticality, it would have been obvious to one of ordinary skill in the art to determine the optimum volumes of the chambers based merely on the specifics of the dialysis method to be performed in the device while maintaining the desired efficiency of the system.

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15. Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al.(Biotech. Prog.) in view of Medicus et al.(US 4,450,076) and Alakhov et al.(US 5,478,730).

The combination of the references of Kim et al. and Medicus et al. has been discussed above.

While the reference of Kim et al. discloses the use of a semipermeable membrane the reference is silent as to the pore size of the membrane.

The reference of Alakhov et al. discloses that when performing a polypeptide synthesis as disclosed by the reference of Kim et al. it is known in the art to employ a semipermeable membrane with a pore size of 100kD or less (See column 4, lines 38-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a membrane of a pore size which is known in the art (100kD or less) for the control of reactants and products in the dialysis system.

16. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al.(Biotech. Prog.) in view of Medicus et al.(US 4,450,076) and Rothschild et al.(US 5,948,624).

The combination of the references of Kim et al. and Medicus et al. has been discussed above.

The above claims differ by reciting that the wells are coated with streptactin, avidin or streptavidin.

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The reference of Rothschild et al. discloses that it is known in the art to immobilize avidin or streptavidin on a solid surface (microtiter wells) so as to isolate chemical, biochemical or biological materials (See column 18, lines 57-67).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the wells of the modified primary reference with immobilized avidin or streptavidin for the known and expected result of providing a means recognized in the art for purification of the polypeptide product produced by the dialysis reaction.

### *Conclusion*

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references of Ainis (US 3,275,528) and Minchinton (US 5,602,028) are cited as prior art references which pertain to culture devices which include semipermeable membranes between separated chambers and the devices include agitators.

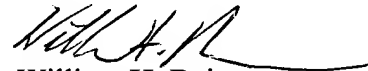
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB  
September 19, 2002